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EXAMINER

WYSZOMIERSKI, GEORGE P

ART UNIT

PAPER NUMBER

1742

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/694,646

Applicant(s)

PATEL ET AL.

Examiner

George P. Wyszomierski

Art Unit

1742

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/9/04, 2/9/05, 2/26/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, 22 and 23, drawn to a product, classified in class 148, subclass 402.
- II. Claims 15-21, drawn to a process, classified in class 148, subclass 563.

2. The inventions are independent or distinct, each from the other because:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by a materially different process, such as a vapor deposition process.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. During a telephone conversation with John Nagy on March 20, 2007 a

provisional election was made without traverse to prosecute the invention of Group I, claims 1-14, 22 and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Interpretation

5. a) The claimed materials in each of independent claims 1, 10 and 22 include a binary nickel-titanium alloy including 54.5-57.0 weight percent nickel. By the examiner's calculations, this is equivalent to approximately 49.4-52.0 atomic percent nickel.

b) A number of the instant claims are written in product-by-process terms. Any process steps in these claims will be given weight only to the extent that they have a material effect on some aspect of the final products produced thereby.

6. Claims 1-14, 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each of claims 1, 10 and 22, the phrase "in an ingot state" does not appear to be appropriate. The materials being defined are in various shapes (e.g. wire, ribbon, sleeve) that would not be equivalent to an ingot. Claims dependent upon any of the above are likewise rejected under this statute.

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7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Beard (PG Pub. 2002/0005047).

Beard discloses Ni-Ti wires that are round in cross section, and have a composition, an A_f temperature, an ultimate tensile strength, and an elongation value as presently claimed. Note particularly Alloy #1 in paragraph [0007] of Beard. Thus, all physical aspects of the claimed invention appear to be fully disclosed (in the sense of 35 USC 102) by the Beard reference.

Beard does not specify that the material disclosed therein has undergone a cold work and anneal cycle, i.e the process steps recited in product-by-process terms in claim 1, or the conditions under which elongation and tensile strength were measured. However, it is well settled that a product-by-process claim defines a product, and that when the prior art discloses a product substantially the same as that being claimed, differing only in the manner by which it is made, the burden falls to applicant to show that any process steps associated therewith result in a product materially different from that disclosed in the prior art. See *In re Brown* (173 USPQ 685) and *In re Fessman* (180 USPQ 524). Given that all composition, shape, and mechanical

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properties as claimed are present in the Beard materials, Applicant has not met this burden. With regard to the testing conditions, it is a reasonable assumption that testing was conducted under standard conditions by Beard, in the absence of any particular statement to the contrary. Thus, at a minimum, the claimed invention is held to have been obvious to one of ordinary skill in the art from the disclosure of Beard.

9. Claims 7, 8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beard.

With respect to claims 7 and 8, Alloy #1 of Beard is stated to contain <0.5% of C, O and Fe, which overlaps the amounts recited in the instant claims. Beard makes no mention of Cu, H, or "any other single trace element" and therefore the examiner assumes that the amounts of these elements in the Beard materials are negligible. Thus, no patentable distinction is seen between this aspect of the claimed invention and the Beard disclosure. With respect to claims 10-14, Beard does not specify the fatigue life value as presently claimed. However, given that the Beard material appears to be identical in every readily identifiable way to the claimed material (composition, shape, various mechanical properties) it is a reasonable assumption that the fatigue life of the prior art materials would likewise be substantially the same as that of the claimed materials. Thus, a prima facie case of obviousness is established between the disclosure of Beard and the presently claimed invention.

10. Claims 5, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beard, as above, in view of Ishibe et al. (U.S. Patent 5,230,348).

With respect to claim 5, while Beard does not appear to disclose any polygonal cross-section shaped materials, Beard paragraph [0011] states that the prior art materials may be

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formed into wires, rods or other shapes. Then, Ishibe Figures 5-9 indicate that polygonal cross-section materials were known to be equivalent in the art to the round cross-section materials disclosed by Beard, in the context of wires made from Ti-55.8%Ni alloy materials.

With respect to claims 22 and 23, Beard paragraph [0019] indicates that the prior art material may be made in the form of a plurality of braided wires, i.e. analogous to that defined in claim 23. Beard does not specify a "medical device for implantation" as required by the instant claims. However, it is unclear what particular physical form is implied by this limitation, as medical devices may be formed into a wide variety of shapes for diverse applications. Ishibe indicates that it was known in the art, at the time of the invention, to employ Ti-55.8%Ni wires (the same material as Beard) as guide wires for catheters, i.e. as medical devices. All statements made in item no. 8 supra with regard to product-by-process limitations and testing conditions apply equally as well in this instance.

Thus, the combined disclosures of Beard and Ishibe et al. would have taught the invention as presently claimed to one of ordinary skill in the art.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Beard, alone or in view of either Iwai et al. (U.S. Patent 5,334,294) or Wang et al. (U.S. Patent 6,375,826).

Beard, discussed supra, does not appear to disclose a surface that is at least partially polished. However, the purpose of Beard is to make jewelry, and it is thus a reasonable assumption that one of skill in the art would want to have a polished, aesthetically pleasing surface in the materials of Beard. In any event, both Iwai and Wang indicate that it was known in the art, at the time of the invention, to electropolish wires made of Ni-Ti alloy, i.e. a material analogous to that of Beard. This allows one to achieve a very smooth surface of a desired

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shape. Thus, the disclosure of Beard, combined with that of Iwai et al. or Wang et al., would have taught the presently claimed invention to one of ordinary skill in the art.

12. The Drawings filed October 27, 2003 are objected to because figures 1-5 include shaded areas with writing or other material that is not legible due to the shading.


Corrected drawings are required in response to this Office Action.

13. The remainder of the art cited on the attached PTO-892 and 1449 forms is of interest. This art is held to be no more relevant to the claimed invention than the art as applied in the rejections, supra.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Wyszomierski whose telephone number is (571) 272-1252. The examiner can normally be reached on Monday thru Friday from 8:00 a.m. to 4:30 p.m. Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King, can be reached on (571) 272-1244. All patent application related correspondence transmitted by facsimile must be directed to the central facsimile number, (571)-273-8300. This Central FAX Number is the result of relocating the Central FAX server to the Office's Alexandria, Virginia campus.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



GEORGE WYSZOMIERSKI
PRIMARY EXAMINER
GROUP 1742

GPW
March 22, 2007